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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,590	09/30/1998	JEFFREY SCHLOM	701433	8846

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EXAMINER
CANELLA, KAREN A

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/155,590	SCHLOM ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-15, 25, 27, 32-34, 66-68, 70-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 11-15 have been amended. Claims 11-15, 25, 27, 32-34, 66-68 and 70-72 are pending and under consideration.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re wands, 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 11-14 are drawn to a genus of mutant ras peptides comprising fragments of the amino acid sequence indicated as Xaa1LeuXaa2ValValGlyAlaXaa3GlyVal wherein the fragments retain the Xaa1 residue, and wherein when Xaa2 is Val, then Xaa1 is Tyr, as well as a genus of mutant ras peptides which consists of fragments of the amino acid sequence indicated as Xaa1LeuXaa2ValValGlyAlaXaa3GlyVal wherein the fragments retain the Xaa1 residue, and wherein Xaa2 is Val, then Xaa1 is Tyr.

Claim 15 is drawn to a peptide consisting of between 8 and 13 amino acids, wherein said peptide is SEQ ID NO:15 or a fragment of SEQ ID NO:15, wherein Xaa1 is Tyr, Xaa2 is any amino acid and Xaa3 is Asp.

The originally filed disclosure describes TyrLeuValValValGlyAlaAspGlyVal (SEQ ID NO:11, page 11, lines 8-9) which meet the criteria of the instant claims 11-14 to the extent that when Xaa2 is Val, then Xaa1 is Tyr. The specification further describes the peptides of SEQ ID NO:1-6 (page 10), SEQ ID NO:12 (page 19), and SEQ ID NO: 13 and 10 (page 20). In all of these peptides Xaa2 is Val; but Xaa1 is Lys rather than Tyr. Thus, the specification fails to adequately describe a genus of truncated peptides Xaa1LeuXaa2ValValGlyAlaXaa3GlyValGlyLysSer wherein the fragments retain the Xaa1 residue, and wherein when Xaa2 is Val, then Xaa1 is Tyr or a genus of peptides from 8 to 13 amino acids wherein the peptide is SEQ ID NO:15 or a fragment of SEQ ID NO:15, wherein Xaa1 is Tyr and Xaa3 is Asp..

One of skill in the art would reasonable conclude that applicant was not in possession of the claimed invention at the time of filing.

Applicant argues that the specification as filed adequately describes the claimed genus of peptides and cites the specification at page 10, lines 1-15, page 11, lines 3-10 and original claims 10-24. Applicant points to the disclosed sequences of SEQ ID NO:1-6, 10, 12 and 13 and argues that the disclosure teaches the substitution of Lys with Tyr. This has been considered but not found persuasive. Firstly, SEQ ID NO:10, 12 and 13 are 14-mer peptides and not encompassed in the scope of the instant claims. Secondly, none of SEQ ID NO:1-6 conform to the instant claims wherein when Xaa2 is Val, then Xaa1 is Tyr. Further, as regards the claimed genuses of mutant ras peptides and the eliciting of a peptide-specific human CD8+ CTL immune response, it is noted that one of skill in the art would not be able to identify a peptide which falls within the claimed genus as being able to elicit a peptide-specific human CD8+ CTL immune response without further testing. Therefore, it is concluded that the specification fails to provide an adequate written description of the claimed genuses of peptides.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for peptides which comprise an Tyr anchor residue at position Xaa1, does not reasonably provide enablement for peptides which do not comprise a Tyr anchor residue at

Xaa1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. In re wands, 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir. 1988)..

Claim 15 encompasses mutant ras peptides which are lacking a Try or a Lys as an anchor residue at position Xaa1. The art teaches that point mutated ras peptides which comprised the 9-mer core sequence , but were longer, or of the appropriate length but lacking a relevant anchor were unable to sensitize targets for lysis (Abrams et al, Eur Journal of Immunology, 1996, Vol. 26, pp. 435-443, reference of the IDS submitted March 19, 1999, see page 442, section 3.5). When given the broadest reasonable interpretation, claim 15 includes fragments of SEQ ID NO:15 having no relevant N-terminal or C-terminal anchor residues. One of skill in the art would be subject to undue experimentation in order to use the broadly claimed peptide without Tyrosine at position Xaa1.

Claims 25, 27, 32-34, 66-68 and 70-72 are allowed.

All other rejections and objections as set forth or maintained in the previous Office action are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/
Primary Examiner, Art Unit 1643